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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,800	01/31/2002	John T. McDevitt	5119-00543	6961

7590 12/29/2005

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,800	MCDEVITT ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *342 and 460-494* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *342 and 460-494* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 342, 461-466, 469-471, 476-479, 481-483, 485, 487, 489-490, 492-494 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanadi, 5,342,581, in view of Kurn et al., 4,868,104.

Sanadi discloses the invention substantially as claimed. More specifically, as to claims 342, 493 and 494, Sanadi discloses a sensor array comprising:

a substrate (132), wherein the substrate comprises one or more cavities (i.e., wells 140), (see fig. 7 and col. 6, lines 55-57);

one or more flexible projections (i.e., gasket 158, see col. 6, line 68) positioned over a portion of the top of the cavity (see fig. 7), wherein one or more of the flexible projections are deformable during insertion of the particle into the cavity (see col. 6, line 68, disclosing resilient gaskets). (The gasket is considered to be flexible because if is resilient, and it is considered to be a projection, see 158 in fig. 7).

Although Sanadi teaches that the cavities (140) are for analysis or processing of biological and chemical samples (col. 3, lines 10-13), Sanadi however does not disclose

a particle positioned in the cavities, wherein the particles exhibit a spectroscopic change upon interaction with the analyte. Kurn et al. teach this limitation.

Kurn et al. however teach that particles tagged with a fluorescent compound provides a signal-producing system to detect an analyte (col. 7, lines 16-31 and col. 8, lines 54-56.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide tagged particles as taught by Kurn et al. in the Sanadi cavities because Kurn et al. teach that the particles provide the advantage of producing a detectable signal for detection of analytes. (As to claim 461, Kurn et al. also teach that the particle is about 50 microns.)

Furthermore, the gasket (158) taught by Sanadi is considered to be configured to substantially inhibit displacement of the particle from the cavity during use (see fig. 7). That is, the gasket, being smaller than the opening of the top part of the cavity (i.e., well 140), substantially inhibits displacement of the particle from the cavity when the particle contacts the gasket.

As to the following claims, Sanadi teach the limitations as follows.

As to claim 462, the cavity (140) is configured to substantially contain the particle.

As to claim 463, the sensor array further comprises a cover layer (i.e., top layer or portion of 132) coupled to the substrate and a bottom layer (i.e., bottom layer or portion of 132)) coupled to the substrate (132), wherein the cover layer and the bottom layer are removable. (The cover layer and the bottom layer are considered to be removable because they are capable of being removed.) (Alternatively, as to claim 463,

Sanadi discloses the elements of this claim in the embodiment in figure 10, wherein the substrate is at (192), the cavities are at (216), and the gasket is at (204), the cover layer is at (200) and the bottom layer is at (196)).

As to claim 464, an opening (148, see fig. 7, and col. 6, line 64) is formed in the bottom of the cavity, wherein the opening is configured such that the fluid flows through the cavity and out of the cavity through the opening during use.

As to claim 465, a cover layer (i.e., "plate" in col. 8, lines 23-25) is coupled to the substrate and a bottom layer (240) is coupled to the substrate (200, see fig. 12), wherein the bottom layer is coupled to a bottom surface of the substrate (see fig. 12) and the cover layer is removable (i.e., capable of being removed), and the cover layer comprises an opening (col. 8, line 25) and the bottom layer comprises an opening (see fig. 12) and wherein the opening in the cover layer and the opening in the bottom layer are substantially aligned with the cavity during use (col. 8, lines 25-26 and fig. 12).

As to claim 466, Sanadi discloses the elements of this claim in the embodiment in figure 12, wherein the substrate is at (240), the gasket is at (204), the cover layer (not shown in the drawing) is the plate between gasket 204 and filter 228 (see col. 8, lines 22-25) and the bottom layer is at (238). Thus, the cover layer is coupled to the substrate and a bottom layer (238) is coupled to the substrate (240), wherein the cover layer comprises an opening substantially aligned with the cavity, and wherein the bottom layer comprises an opening substantially aligned with the cavity.

As to claim 469, a cover layer (i.e., "plate" in col. 8, lines 23-25) is coupled to the substrate and a bottom layer (240) is coupled to the substrate, wherein the bottom layer

is configured to support the particle, and wherein the cover layer comprises an opening substantially aligned with the cavity (col. 8, lines 23-26).

As to claim 470, a removable cover layer (i.e., "plate" in col. 8, lines 23-25) is coupled to the substrate.

As to claim 471, the substrate comprises a plastic material (col. 7, line 42).

As to claim 476, the sensor array further comprises channels (236, in fig. 12) in the substrate, wherein the channels are configured to allow the fluid to flow through the channels into and away from the cavity (col. 8, lines 14-20).

As to claim 477, a plurality of additional particles are positioned within a plurality of additional cavities in the substrate (see fig. 2).

As to claim 478, a plurality of additional flexible projections are positioned over a plurality of additional cavities in the substrate (see fig. 2).

As to claim 479, the sensor array further comprises a cover layer (i.e., "plate", col., 8, lines 23-25) coupled to the substrate, wherein at least one of the flexible projections (204) is formed in the cover layer (see fig. 12).

As to claim 481, at least one of the flexible projections comprises plastic (col. 7, line 42).

As to claim 482, the flexible projection (204) is configured to retain the particle in the cavity.

As to claim 483, the sensor array further comprises a top opening and a bottom opening of the cavity (see fig. 12) and provides selection of the particle substantially contained in the cavity.

As to claim 485, the particle is capable of being positioned within the cavity by using airflow to pull the particle through the flexible projection.

As to claim 487, the flexible projection is transparent (see styrene copolymer material, col. 5, line 7) to the light generated by a light source.

As to claim 489, the flexible projection (158) is configured to elastically bend into the cavity in the substrate (because it is resilient and is capable of bending into the cavity), (see col. 6, line 68).

As to claim 490, the sensor array further comprises a mask (212 in the embodiment in fig. 10) configured to inhibit bending of at least one of the flexible projections (204) from an initial position to a position away from the cavity.

As to claim 492, the flexible projection (204) is configured to elastically bend into the cavity in the substrate, and the flexible projection is configured to be inhibited from bending away from the cavity (see fig. 10).

2. Claims 473 and 474 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanadi, 5,342,581, in view of Kurn et al., 4,868,104, as applied to claim 342, and further in view of Burns et al., 6,379,929.

Sanadi in view of Kurn et al. teach the invention substantially as claimed (see claim 342 above), except for the substrate comprising a dry film photoresist material (claim 473), and except for the substrate comprising a plurality of layers of a dry film photoresist material (claim 474).

Burns et al. however teach that layers of photoresist is used as the sacrificial layers to define a hole for the manufacturing of an assay device (col. 79, lines 37-44.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide layers of photoresist as taught by Burns et al. in the Sanadi multiwell plate because Burns et al. teach that the layers of photoresist provide the advantage of serving as sacrificial layers for the production of holes in the manufacturing of an assay device, such as the Sanadi wells.

3. Claim 475 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanadi, 5,342,581, in view of Kurn et al., 4,868,104, as applied to claim 342, and further in view of Oldenburg et al., 6,027,695.

Sanadi in view of Kurn et al. teach the invention substantially as claimed (see above with respect to claim 342), except for an inner surface of the cavity being coated with a reflective material.

Oldenburg et al. however teach that a microtiter plate that is formed of a highly reflective material enhances the performance of the microtiter plate when used for measurement of luminescence (col. 8, lines 30-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made provide a reflective material as taught by Oldenburg et al. on the inside of the Sanadi wells because Oldenburg et al. teach that the reflective material provides the advantage of enhancing the performance of the wells when used for measurement of luminescence.

4. Claims 342, 460, 467, 468, 472, 484 and 488 are rejected under 35 U.S.C. 102(b) as being anticipated by Lavigne et al., "Solution-Based Analysis of Multiple Analytes by a Sensor Array: Toward the Development of an "Electronic Tongue"", J. American Chemical Society, Vol. 120, pp. 6429-6430, in view of Sanadi, 5,342,581.

Lavigne et al. teach the invention substantially as claimed. More specifically, as to claim 342, Lavigne et al. teaches a sensor array comprising:

a substrate (chip (page 6429, line 4), wherein the substrate comprises at least one cavity (wells, page 6429, line 3);

a particle (bead, page 6429, line 3) positioned within the cavity, wherein the particle exhibits a spectroscopic change upon interaction with the analyte (page 6430, left column); and

However, Lavigne et al. do not teach a flexible projection positioned over a portion of the cavity, wherein the flexible projection is configured to substantially inhibit displacement of the particle from the cavity during use and wherein the flexible projections are deformable during insertion of the particle into the cavity. Sanadi et al. teach these limitations.

Sanadi et al. teach using a gasket over a plate of wells in order to form a hermetic seal with a lid such that the apparatus can be placed in various orientations without movement of the samples from their container (see col. 3, lines 25-31, col. 4, lines 27-28, col. 5, lines 8-10 and col. 8, lines 65-67.) It would have been obvious to

one of ordinary skill in the art at the time the invention was made to provide a gasket as taught by Sanadi et al. on the top of the Lavigne wells because Sanadi et al. teach that the gasket provides the advantage of providing a hermetic seal to contain the samples in the wells. (The gasket taught by Sanadi et al. is considered to be the claimed flexible projection.)

As to the following claims, Lavigne et al. teach the limitations as follows.

As to claim 460, the particle comprises a receptor molecule coupled to a polymeric resin (page 6429, third paragraph).

As to claim 467, the cavity is tapered such that the width of the cavity narrows in a direction from a top surface of the substrate toward a bottom surface of the substrate, and a minimum width of the cavity is substantially less than a width of the particle (see figure 1 C).

As to claim 468, a width of a bottom portion of the cavity is substantially less than a width of a top portion of the cavity, and the width of the bottom portion of the cavity is substantially less than a width of the particle (see figure 1 C).

As to claim 472, the substrate comprises a silicon wafer (page 6429, right column, line 3).

As to claim 484, a size of the particle is smaller than a top opening of the cavity and larger than a bottom opening of the cavity such that the particle will be substantially contained in the cavity (see page 6430, figure 1 (C)).

As to claim 488, the sensor array further comprises a cover layer (cover plate, page 6430, see description of Figure 1) coupled to the substrate and a bottom layer

coupled to the substrate (i.e., bottom layer of wafer, page 6429, line 3), wherein the cover layer and the bottom layer are transparent to light generated by a light source (page 6430, see description of Figure 1, and page 6429, line 3).

5. Claim 480 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanadi, 5,342,581, in view of Kurn et al., 4,868,104, as applied to claim 342, and further in view of Flannery et al., 6,517,736.

Sanadi in view of Kurn et al. disclose the invention substantially as claimed (see above with respect to claim 342), except for the flexible projections being comprised of silicon nitride.

Flannery et al. however teach that gaskets (i.e., the claimed flexible projections) use to seal layers of a microfluidic channel together (col. 3, lines 39-40) are preferably made of silicon nitride (see abstract, last sentence). It would have been obvious to one of ordinary skill in the art at the time the invention was made utilize silicon nitride as the material for the Sanadi gasket because Flannery et al. teach that a gasket formed of such material provides the advantage of sealing layers together such as the Sanadi layers in the well plate.

6. Claim 486 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanadi, 5,342,581, in view of Kurn et al., 4,868,104, as applied to claim 342, and further in view of Kale et al., 5,849,823.

Sanadi in view of Kurn et al. disclose the invention substantially as claimed (see above with respect to claim 342), except for the flexible projections being formed of silicon dioxide.

Kale et al. however teach that gaskets (i.e., the claimed flexible projections) formed from a polymer mixture may also contain additives such as silicon dioxide to enhance antiblocking, mold release and coefficient of friction characteristics to facilitate the manufacturing of the gasket (col. 10, lines 24-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide silicon dioxide in the Sanadi gasket as taught by Kale et al. because Kale et al. teach that such an additive provides the advantage of enhancing antiblocking, mold release and coefficient of friction characteristics to facilitate the manufacturing of the gasket.

7. Claims 342, 491, 493, 494 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al., 6,929,030, in view of Kurn et al., 4,868,104.

Unger et al. disclose the invention substantially as claimed. More specifically, as to claims 342 and 493, Unger et al. disclose a sensor array comprising:

a substrate (7708), wherein the substrate comprises one or more cavities (7710);

one or more flexible projections (7712) positioned over a portion of the top of the cavity (see fig. 72), wherein one or more of the flexible projections are deformable during insertion of the particle into the cavity (see col. 25, lines 24-26). (As to claim 494, a plurality of cavities is disclosed in Fig. 74.)

As to claim 491, Unger et al. teach that the flexible projection is electrically actuated to allow insertion of the particle into the cavity (see col. 25, lines 43-54).

Although Unger et al. teach that the device is used for sorting and/or detection of various sample components using a variety of techniques such as fluorescence (col. 47, lines 48-53), Unger et al. however do not specifically disclose a particle positioned in the cavities, wherein the particles exhibit a spectroscopic change upon interaction with the analyte. Kurn et al. teach this limitation however.

Kurn et al. however teach that particles tagged with a fluorescent compound provides a signal-producing system to detect an analyte (col. 7, lines 16-31 and col. 8, lines 54-56.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide tagged particles as taught by Kurn et al. in the Van Dam cavities because Kurn et al. teach that the particles provide the advantage of producing a detectable signal for detection of analytes.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Van Dam et al., 6,508,988, discloses a substrate (100), with cavities (104), a flexible projection (20), electrically actuated (col. 19, lines 45-55).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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